K132409

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4160 (801) 826-4171 Vicki Godwin August 1,2013 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Concierge® Guiding Catheter Guiding Catheter Percutaneous Catheter
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Concierge® Guiding Catheter Percutaneous Catheter K121051 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1250 FDA Product Code: DQY Review Panel: Cardiovascular	
Intended Use	The Concierge Guiding Catheter is intended for the intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.	
Device Description	The Concierge Guiding Catheter is a single lumen catheter that incorporates a Pebax body reinforced with stainless steel wire braid, a PTFE lubricious inner lumen, and a soft radiopaque tip. It is available in 5F, 6F, 7F and 8F sizes, 100cm long and is produced in a variety of shapes.	

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Comparison to Predicate Device	The technological characteristics of the subject Concierge Guiding Catheters are substantially equivalent to those of the predicate device. The 5F, 7F and 8F Concierge Guiding Catheter sizes are modifications of the predicate 6F Concierge Guiding Catheter. In addition, changes were made to the device material and packaging that affects the entire Concierge Guiding Catheter product line.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Concierge Guiding Catheter was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 10555-1:1995, *Sterile, single-use intravascular catheters – Part 1: General requirements* • ISO 10555-2:1996, *Sterile, single-use intravascular catheters – Part 2: Angiographic catheters* • ISO 11135-1: 2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* • ISO 10993-1: 2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process* • ISO 10993-5: 2009, *Biological Evaluation of Medical Devices Part-5: Tests for In Vitro Cytotoxicity* • ISO 10993-7: 2008, *Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals* • ISO 10993-17: 2002, *Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances* • ISO 10993-18: 2005, *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials* • ISO 2233: 2000: *Packaging – complete, filled transport packages and unit loads – conditioning and testing* • BS EN ISO 11607: 2009, *Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)* • ASTM D4169-09: 2009, *Standard practice for performance testing of shipping containers and systems* • ASTM F756-08, 2008: *Standard Practice for Assessment of Hemolytic Properties of Materials* • ASTM F1929-98(2004): 1998, *Standard test method for detecting seal leaks in porous medical packaging by dye penetration*

	• ASTM F2096-11: 2011, *Standard test method for detecting gross leaks in medical packaging by internal pressurization (bubble test)* • ASTM F88/F88M-09: 2009 *Standard test method for seal strength of flexible barrier materials* • ASTM F1140-07, *Standard test methods for internal pressurization failure resistance of unrestrained packages* The following is a list of all significant testing that was successfully completed: <u>Device Testing</u> • Dimensions • Air Leak • Liquid Leak • Catheter Tip Support and Attachment • Tensile • Shaft Kink • Shaft Stiffness • Simulated use testing <u>Packaging testing</u> • Visual Inspection • Dye Penetration • Underwater Leak Test • Seal Peel Tensile Test • Burst Strength Test • Aseptic Peel Opening <u>Biocompatibility testing</u> • Cytotoxicity • Hemocompatibility • Chemical Characterization The results of the testing demonstrated that the subject Concierge Guiding Catheters met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.
Safety & Performance Tests cont.	
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Concierge Guiding Catheters meet the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Concierge Guiding Catheter, manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

Merit Medical Systems, Inc.
c/o Vicki Godwin
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K132409
Trade/Device Name: Concierge Guiding Catheter
Regulation Number: 21 CFR § 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 1, 2013
Received: August 2, 2013

Dear Ms. Godwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K132409

Device Name: Concierge® Guiding Catheter

Indications for Use:
The Concierge® Guiding Catheter is intended for the intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)